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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/729,028	12/04/2000	Shiguang Yu	6560	4708

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EXAMINER

OSTRUP, CLINTON T

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 02/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application N .

09/729,028

Applicant(s)

YU ET AL.

Examiner

Clinton Ostrup

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 15-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

Claims 15-25 are pending in this application.

***Response to Applicants' Arguments/Amendments***

**35 USC § 112**

The Applicants' Amendments and Arguments filed January 4, 2002, Paper No.3, to the 35 USC § 112 Second Paragraph rejections of claims 1-14 has been rendered moot because applicants' have canceled claims 1-14.

**35 USC § 102**

The rejection of claims 1-4, 6-11, and 14 under 35 U.S.C. 102(b) as being unpatentable over Schwen et al 5,344,651 is now applied to newly added claims 15-16, 18, and 21 for the reason set forth in the Office Action mailed September 13, 2001, and those found below.

Applicant argues that Schwen is directed to complex steroidal compositions to regulate hair growth and that all kinds of carriers are disclosed by Schwen including solid, semi-solid and liquid carriers. Applicant essentially argues that the examiner has used hindsight not foresight to arrive at applicants' invention. Applicant further argues that there is no directed disclosure in Schwen which combines the alcohols with the specific condition claimed in claim 15 the state wherein alopecia has occurred and accelerating hair growth in that particular area.

Applicant then argues limitations of claims 22-25 which are not rejected under 35 U.S.C. 102(b).

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In response to applicants' assertion that the examiner used hindsight to arrive at applicants' invention, the examiner points to Example 21 wherein ethanol is clearly used in a shampoo composition. Furthermore, the Schwen describes how "Preferably the solution form of the present invention will comprise a safe and effective amount of CATA, the balance being water and/or a suitable organic solvent. The organic solvents are those typically used in the art such as ethanol and isopropanol. Although applicant does not intend CATA to be included in their invention, the fact that Schwen uses ethanol in a shampoo formulation for topical application to regulate hair growth and teaches isopropanol and ethanol as suitable solvents in the preferred solution form of their composition, Schwen clearly anticipates instant claims 15-16, 18 and 21.

### **35 USC § 103**

The rejection of claims 1-12 and 14 under 35 U.S.C. 103(a) as being unpatentable over Gibson **4,871,839** and further in view of Schwen et al **5,344,651** as applied to claims 1-4, and 6-11, and 14 above is now applied to newly added claims 15-19, and 21-23, and 25 for the reason set forth in the Office Action mailed September 13, 2001, and those found below.

Applicants' argue that Gibson is restricted to humans and state that there is no mention of lower mammals and there is no disclosure as to alopecia. Applicants' further argue that the number of materials cited to deliver monoxidil derivatives... is enormous and that there is no indication that any of the alcohols cited will cause hair to grow faster after alopecia has occurred in a dog or a cat.

Examiner respectfully disagrees. Claims 1-12 and 14 were rejected under 35 U.S.C. 103(a) as being unpatentable over Gibson **4,871,839** and further in view of Schwen et al **5,344,651**, not over Gibson alone. Gibson teaches compositions which are particularly suited to stimulate hair growth or regrowth and Schwen provides the skilled artisan with the motivation to use a hair treatment composition suited for human use on domestic animals, such as dogs and cats. Gibson teaches ethyl alcohol and isopropanol as solvents and exemplifies the use of ethanol in Examples 1-8. Finally, the definition of alopecia is the loss of hair, therefore, both Gibson and Schwen teach topically applying compositions to treat alopecia.

The rejection of claim 13 under 35 U.S.C. 103(a) as being unpatentable over Schwen et al **5,344,651** and further in view of Jacques et al **4,775,361** as applied to claims 1-12 and 14 in the Office Action mailed September 13, 2001, and those found below is now applied to newly added claims 20 and 24.

Applicants' argue that Schwen disclose nothing about the removal of a portion of the stratum corneum prior to the application of alcohol and that the Jacques reference is limited to humans and that the therapeutic substances disclosed by Jacques does not include alcohol.

Examiner respectfully agrees that Jacques does not disclose alcohol as a therapeutic substance and that Schwen does not disclose the benefits of removing the stratum layer. However, the examiner disagrees that a skilled artisan would not be motivated to combine the methods of Jacques with the compositions of Schwen to treat lower mammals, such as cats and dogs, as discussed in Paper No. 2. Furthermore, as

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discussed above Schwen provides the motivation to apply the methods and compositions for growing hair on humans to domestic animals, such as cats and dogs.

***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 15-16, 18 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Schwen et al 5,344,651.

Schwen et al teach methods of regulating hair growth by topical application of compositions comprising cyproterone acetate thioacetate (CATA). The reference describes how domestic animals such as cats and dogs suffer from hair loss and teaches methods for regulating hair loss by topical application of said compositions. The reference describes liquid formulations of the compositions as comprising a solution of a safe and effective amount of CATA and the balance being a mixture of water and/or a suitable organic solvent. Ethanol, isopropanol, or mixtures thereof are then described as organic materials useful as solvents or as part of a solvent system, therefore, Schwen et al meets the specific limitations of instant claims 15-16, 18, and 20. See: col. 1 lines 5-8; col. 2, lines 62-67; col.6, lines 3-13; and col. 11, lines 41-55.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 15-19, 21-23, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gibson **4,871,839** and further in view of Schwen et al **5,344,651** as applied to claims 15-16, 18, and 20 above.

Gibson teaches skin treatment compositions which are particularly suited to stimulate hair growth or regrowth. The primary reference discloses vehicles for topically administering formulations comprising minoxidil glucuronide. The vehicles are described as water and/or at least one cosmetically acceptable vehicle which can comprise from 10 to 99.999% by weight of the composition. The primary reference teaches ethyl alcohol (ethanol) and isopropanol as solvents, which can be used as cosmetically acceptable vehicles. See: col. 6, line 30 – col. 7, line 40.

Although Gibson describes using ethanol and isopropanol containing compounds in concentrations, which overlap those of instant claims 19 and 25 to grow hair, Gibson does not specifically teach using these compounds to grow hair on canines and felines.

Schwen et al teach methods of hair growth comprising application of cyproterone acetate thioacetate (CATA) and compositions comprising CATA. The reference describes how domestic animals such as cats and dogs suffer from hair loss and describes methods for regulating hair loss by topical application of compositions containing alcohol. The secondary reference teaches ethanol, isopropanol, or mixtures thereof as the solvents or as part of a solvent system. See: col. 1 lines 5-8; col. 2, lines 62-67; col.6, lines 3-13; and col. 11, lines 41-55.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the method of using the hair growth compositions

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of Gibson by topically applying the hair growth compositions to canines and felines as taught by Schwen et al, because of the expectation of obtaining a method of regulating hair growth in domestic animals such as cats and dogs.

Claims 20 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwen et al as applied to claim 15-19, 21-23, and 25 above, and further in view of Jacques et al **4,775,361**.

Schwen et al teach the topical application of compositions comprising ethanol and isopropanol and the use of said compositions as regulating hair growth in domestic animals including cats and dogs, however, Schwen et al do not specifically teach the removal of a portion of the stratum corneum prior to the application of alcohol as in claim 20 and 24.

Jacques et al disclose a method of administering a polar therapeutic substance by first removing the stratum corneum to enhance percutaneous transport and then applying the polar therapeutic substance. The secondary reference specifically discloses tape stripping as a method of removing the stratum corneum and applying the therapeutic substance after the stratum corneum has been removed. See: col. 1, lines 5-32.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the methods of using a the topical hair growth composition of Schwen et al. by removing the stratum corneum by tape stripping as taught by Jacques et al because of the expectation of obtaining a method of applying a



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topical hair growth composition for percutaneous transport which does not have to overcome the skin barrier function of the stratum corneum.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Clinton Ostrup whose telephone number is (703) 308-3627. The examiner can normally be reached on M-F (8:30am-5:00pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703)

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308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Clinton Ostrup  
Examiner  
Art Unit 1614

February 4, 2002

FILED IN CASES  
PRIMARY EXAMINER  
(GROUP 1600)

